

K100162

BIOGREEN YIELDS SDN. BHD.

LOT 1422, BATU 10 LEKIR
32020 SITIAWAN, PERAK, MALAYSIA

MAR 24 2010

510(k) SUMMARY

BIOGREEN YIELDS SDN. BHD.

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510 (K) SUMMARY SHEETS

1.0

SMDA 510 (K) SUMMARY

2.0 Submitter

BIOGREEN YIELDS SDN. BHD.,
Lot 1422, Batu 10 Lekir
32020 Sitiawan, Perak
Malaysia

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605-6792288

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605-6791188

Name of Contact Person

1. Mr. Tiong Chiong Kieng
2. Mr. Arivalagan

Date of Summary Prepared

January 5, 2010

3.0 Name of Device

Trade Name: Non-Sterile, Blue Color Powder Free Nitrile Examination Glove

Common Name: Synthetic Rubber Examination Gloves

Classification Name: Patient Examination Glove, Powder Free

4.0 Identification of The Legally Marketed Devices

Non Sterile Powder Free Nitrile Examination Gloves as described in this 510k Notification is substantially equivalent to the current Class I patient examination glove bearing the product code 80LZA (21CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D6319-05, Standard Specification for Nitrile Gloves for Medical Application.

5.0 Description of The Device

Non Sterile Powder Free Nitrile Examination Gloves meets all the current specifications listed under the ASTM Specification D6319-05, Standard Specification for Nitrile Examination Gloves for Medical Application.

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6.0 The Intended Use of Glove

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. This device is for over-the counter use.

7.0 Summary of Performance Data:

Performance data of gloves based on ASTM D6319-05 and FDA 1000ML watertight test.

Test	FDA 1000ml Water Leak Test	Powder Free Nitrile Examination Gloves
1. Watertight (1000ml)	Multiple Normal GI AQL = 2.5	Pass
Test	ASTM D6319-05	
2. Length (mm) Size M L XL	Min 230 Min 230 -	240 - 248
3. Palm width (mm) Size M	95 ± 10	95 - 98
4. Thickness (mm) (Single Layer) Finger Palm	Min 0.05 Min 0.05	0.08 - 0.09 0.06 - 0.07
5. Physical Properties Before Aging Tensile Strength (MPa) Ultimate Elongation (%) After Aging Tensile Strength (MPa) Ultimate Elongation (%)	Min 14 Min 500 Min 14 Min 400	22 - 32 710 - 750 22 - 29 630 - 690
6. Powder Content	Max 2.0mg/glove	Below 2 mg/glove
7. Moisture Content	Max 2.0%	0.57%

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8.0 The performance data of the glove as shown above meet the ASTM D6319-05 Standard and FDA's requirement.
Powder content is below 2 mg per glove which meet the FDA Requirements.

9.0 The Bio-compatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buehler) test.
The gloves pass the Bio-compatibility Test.

10.0 Conclusion

We conclude that the Non-Sterile, Blue Color Powder Free Nitrile Examination Gloves meets:

- ASTM D6319-05 Standard
- FDA pinhole requirements
- Are below the maximum Powder Residual Content as specified in ASTM D6319-05



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 20 2010

Mr. Tiong Chiong Kieng
Director
Biogreen Yields Sdn. Bhd
Lot 1422 Batu 10 Lekir
Sitiawan Perak
MALAYSIA 32020

Re: K100162

Trade/Device Name: Non Sterile, Blue Color Powder Free Nitrile
Examination Gloves

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA

Dated: January 5, 2010

Received: January 20, 2010

Dear Mr. Kieng:

This letter corrects our substantially equivalent letter of March 24, 2010

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

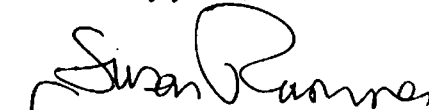
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony Watson", is written over the typed name.

Anthony Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K100162

Indications for Use

510(k) Number (if known): K100162

Device Name: Non Sterile, Blue Color Powder Free Nitrile Examination Gloves

Indications For Use:

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. This device is for over-the counter use.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____ / ____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of ____


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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